

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PU3375/PCT	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP98/06278	International filing date (day/month/year) 05/10/1998	Priority date (day/month/year) 07/10/1997	
International Patent Classification (IPC) or national classification and IPC A61K31/00			
Applicant GLAXO GROUP LIMITED et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  05/05/1999	Date of completion of this report  23.02.00
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Cattell, James  Telephone No. +49 89 2399 8468



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP98/06278

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-15 as originally filed

**Claims, No.:**

1-10 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.  
☒ claims Nos. 4, 8 (1, 5, 9 partially), 5-7(IA) .

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP98/06278

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 1, 4, 5, 8, 9.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

**see separate sheet**

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 2, 3, 6-7, 10 (1, 5, 9 partially).

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP98/06278

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1, 2, 3, 5, 6, 7
	No:	Claims	9, 19
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1, 2, 3, 5, 6, 7
Industrial applicability (IA)	Yes:	Claims	1, 2, 3, 9, 10
	No:	Claims	

**2. Citations and explanations**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/EP98/06278

III.

1. An international examination report can only be drawn up on searched subject-matter (Rule 66.1(e) PCT).
2. Claims 5, 6 and 7 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

IV.

- 3 The IPEA agree with the assessment of unity made by the ISA under Rule 13.1 PCT. Once it is known and obvious that 5-HT<sub>3</sub> receptor antagonists can be used to treat IBS (see section V below) the use of the individual agents exemplified in claim 8 are regarded as being different "inventions".

V.

4. Document D1 (EP-A-0,306,323) discloses on page 4 lines 1 and 26 the use of alosetron to treat IBS.  
Document D2 (Foster et al 1997) and D3 (Barman et al 1996) disclose the use of alosetron to treat IBS.  
These disclosures fall within the scope of product claims 9 and 10 under Article 33(2) PCT.
5. Once the use of alosetron in IBS patients is known (from an one of D1 to D3) the optimisation of the treatment would be obvious. The discovery of treating female nonconstipated IBS patients would occur inevitable from these obvious trials.  
Claims 1, 2, 3, 5, 6 and 7 therefore do not meet the requirements of Article 33(3) PCT.

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Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Cattell, James  Telephone No. +49 89 2399 8468



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	No: Claims 9, 19
Inventive step (IS)	Yes: Claims
	No: Claims 1, 2, 3, 5, 6, 7
Industrial applicability (IA)	Yes: Claims 1, 2, 3, 9, 10
	No: Claims

**2. Citations and explanations**

**see separate sheet**

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